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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/095,385 06/10/98 MORRISON S 30435.45USU1

GATES & COOPER
HOWARD HUDHES CENTER
6701 CENTER DRIVE WEST, SUITE 1050
LOS ANGELES CA 90045

HM22/1120

EXAMINER

ZEMAN, M

ART UNIT	PAPER NUMBER
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1631

DATE MAILED:

11/20/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/095,385

Applicant(s)

MORRISON ET AL.

Examiner

Mary K Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 15-33 is/are pending in the application.
- 4a) Of the above claim(s) 16-27 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-13 and 28-33 is/are allowed.
- 6) ☒ Claim(s) 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

Claims 1-13 and 15-33 are pending in this application.

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 16-21 been renumbered 28-33.

Claims 16-27 stand previously withdrawn from consideration and **must be canceled** in response to this Action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 15 is rejected under 35 U.S.C. 102(e) as being anticipated by Weltzin et al. (US Patent 5,534,411).

Claim 15 is product-by-process type claim, wherein the claim is drawn to a product (secretory Ig) made by a particular process (transfection of an Ig producing cell with SC). This claim should have been rejected in the previous action, and was omitted due to oversight.

The MPEP discusses product-by -process claims in chapter 2100: "Even though product-by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by -process claim is the same as, or obvious from a product in the prior art, the claim is unpatentable even though the prior product was made by a different process." See MPEP 2113.

Weltzin et al. sets forth recombinant IgA molecules that comprise secretory component. The methods of Weltzin et al. are very similar to those of the claimed invention. Whether the product resulting from the process is the same, is not clear, and the Office does not have the facilities to perform such comparative analyses. In a discussion of product-by-process claims, this court has said: "[W]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process

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claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 59 CCPA 1036, 1041, 459 F.2d 531, 535, 173 USPQ 685, 688 (1972). The court further addressed the issue of product-by process claims in *In re Best*: "the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on 'inherency' under 35 USC 102, on 'prima facie obviousness' under 35 USC 103, jointly or alternatively, the burden of proof is the same [footnote omitted]." *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977). Applicant argues that because the antibodies are made by a differing process, the resulting antibodies are different. Applicant has not provided evidence distinguishing the claimed compositions over the antibodies produced by Weltzin et al.

Claim 15 is rejected under 35 U.S.C. 102(e) as being anticipated by Hein et al (US Patent 5,959,177). As above, this claim should have been rejected in the previous action, and was inadvertently omitted.

Hein et al. set forth recombinant IgA molecules that comprise secretory component. The methods of Hein et al. produce dimeric IgA with Secretory Component that appear to be the same as those being claimed. The antibodies of Hein et al. are secreted, and bind appropriate antigens. Whether the product resulting from the process is the same, is not clear, and the Office does not have the facilities to perform such comparative analyses. In a discussion of product-by-process claims, this court has said: "[W]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 59 CCPA 1036, 1041, 459 F.2d 531, 535, 173 USPQ 685, 688 (1972). The court further addressed the issue of product-by process claims in *In re Best*: "the PTO can require an applicant to prove that the prior art

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products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on 'inherency' under 35 USC 102, on 'prima facie obviousness' under 35 USC 103, jointly or alternatively, the burden of proof is the same [footnote omitted]." In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977). Applicant argues that because the antibodies are made by a differing process, the resulting antibodies are different. Applicant has not provided evidence distinguishing the claimed compositions over the antibodies produced by Weltzin et al.

Conclusion

Claims 1-13 and 28-33 are allowed. Claim 15 stands rejected. Claims 16-27 stand withdrawn from consideration.

The following is a statement of reasons for the indication of allowable subject matter: In review of the art at the time of the invention, the understanding of how secretory antibodies are assembled and secreted was understood to be a quite complex process involving differing types of cells and processing. The art does not teach or suggest that such antibodies could be produced by the simple transfection of an antibody producing cell with DNA encoding secretory component. Nor would one of ordinary skill in the art have expected any resulting antibodies to be functional. Therefore, the methods of the invention are novel and unobvious over the art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The examiner can be reached between the hours of 7:30 am and 5:00 pm Monday through Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308 4028.

The fax number for this Art Unit is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center receptionist whose telephone number is (703) 308-0196.
mkz

November 17, 2000

Mary K Zeman
Examiner, 1631